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NOV 14 2011

SECTION IV K111843

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

ACUFEX Director Application Anatomic Guide System

Date Prepared: Sept. 9th, 2011

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road, Andover MA. 01810

B. Company Contact

Janice Haselton

Sr. Regulatory Affairs Specialist

T 978-749-1494

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C. Device Name

Trade Name:	ACUFEX Director Application Anatomic Guide System
Common Name:	Anatomic Guide
Classification Name:	Orthopedic Stereotaxic Instrument per CFR 882.4560

D. Predicate Devices

The Smith & Nephew ACUFEX Director Application Anatomic Guide System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: VectorVision ACL cleared in K042512.

E. Description of Device

The ACUFEX Director Application Anatomic Guide System is a software based application that allows surgeons to captured intraoperative still images from a medical fluoroscopic C-arm, display them on a touchscreen computer, visually locate anatomic landmarks of the tibia or femoral footprint using various automated overlays for ACL/PCL single or double bundle placements and mark the selected tunnel placement based on the anatomic landmarks.

Prior to use of the ACUFEX Director Application Anatomic Guide System the surgeon places a microfracture awl or other radio opaque positioning aid in the desired position for tunnel placement per the surgical procedure.

The ACUFEX Director Application Anatomic Guide System software automatically generates the pre-selected ACL/PCL overlays and places the marker positions on the touchscreen. The surgeon identifies and marks the patient's anatomic locations. These marker locations are relative to the sizing of the grid defined by the surgeon selected ACL or PCL anatomical points. The surgeon can adjust the size or rotate the overlay to accommodate their pre-selected position or they can accept the overlay markers. If the surgeon decides to accept the overlay markers a re-positioning of the microfracture awl relative to the overlay markers is made. At this point the tunnel location can be drilled over the final location of the microfracture awl.

The touchscreen computer is purchased by Smith & Nephew as an "off the self" product. The major components are the touchscreen computer, keyboard, mouse, and video converter. A mobile cart is offered as part of the system or as an optional accessory.

F. Intended Use

The ACUFEX Director Application Anatomic Guide System is designed to help orthopedic surgeons and specialists access intraoperative images and provides user controlled visual feedback in order to assist in the planning and historical case review of the location of cruciate ligament tunnel insertion sites.

G. Comparison of Technological Characteristics

The proposed ACUFEX Director Application Anatomic Guide System has the following similarities as the predicate device VectorVision ACL cleared in K042512. In that:

- The proposed and predicate devices both have similar indications for use.
- The proposed and predicate devices both utilize the same principle of operation.
    1. Computer assisted planning of operative site
- The proposed and predicate devices both capture diagnostic images for surgeon planning of orthopedic surgery.
- The proposed and predicate devices both use overlays for use in pre-surgical planning.

The major differences between the ACUFEX Director Application Anatomic Guide System and the VectorVision ACL cleared in K042512 are:

- The ACUFEX Director Application Anatomic Guide System only provides a still image from the C-arm for viewing on the monitor whereas the VectorVision ACL creates a virtual, individual 3-D surface model of the patient's bone from the patient's intra-operative image
- The ACUFEX Director Application Anatomic Guide System only provides a still image from the C-arm for viewing on the touchscreen monitor. The VectorVision ACL provides the image using CT, fluoroscopic, x-ray or a MR-based model.
- The ACUFEX Director Application Anatomic Guide System is a stand-alone system and cannot be connected to the hospital network. The VectorVision ACL can be connected to the hospital network in order to access patient and hospital data.
- The predicate device, VectorVision ACL calibrates the image in order to account the x-ray's inherent magnification. The ACUFEX Director Application Anatomic Guide System does not need to calibrate since no absolute measurements are needed.

H. Summary Performance Data

- Software verification and validation testing demonstrates that the ACUFEX Director Application Anatomic Guide System does not raise any new questions of safety and efficacy as compared to the predicate device VectorVision ACL cleared in K042512.
- Cadaver validation.

The ACUFEX Director Application Anatomic Guide System was tested and met compliance with IEC 60601-1-2, Electro-magnetic Compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 14 2011

Smith and Nephew, Inc.
Endoscopy Division
% Ms. Janice Haselton
150 Minuteman Road
Andover, Massachusetts 01810

Re: K111843
Trade/Device Name: ACUFEX Director Application Anatomic Guide System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 03, 2011
Received: November 07, 2011

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111843

Device Name: ACUFEX Director Application Anatomic Guide System

Indications For Use:

The ACUFEX Director Application Anatomic Guide System is designed to help orthopedic surgeons and specialists access images intraoperative and provides user controlled visual feedback in order to assist in the planning and historical case review of the location of cruciate ligament tunnel insertion sites.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111843

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)